MAY 2 8 2004

K040265

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Exhibit VI

510(K) Summary of Safety and Effectiveness

(1)

Submitter's name:	Biocomposites Ltd
Submitter's address:	Etruscan Street, Etruria, Stoke-on-Trent, ST1 5PQ, England
Submitter's telephone number:	44 (0) 1782 206500
Contact person:	Stephen Bratt
Date summary prepared:	27th January 2004

(2)

Trade or proprietary device name:	Little Grafter™ Screw
Common or usual name:	Bone Fixation Screw
Classification name:	Smooth or threaded bone fixation fastener

(3) **Legally marketed predicate device:**

Herbert Bone Screw (Zimmer Inc)	K792022
Acutrak (Acumed Inc)	K944330
Asnis III Screw (Howmedica Osteonics)	K000080
Synthes Compression Screw (Synthes USA)	K021556
Wisorb Malleolar Screw (Cambridge Scientific)	K020222

(4) **Subject device description:**

The Little Grafter™ Screw is a cannulated, sterile, single use bone fixation screw manufactured from a composite mixture of a calcium salt and a bioabsorbable polymer

(5) **Subject device intended use:**

The Little Grafter™ Screw is intended for fixation of fractures of small bones and small bone arthrodeses, including, but not limited to, scaphoid fractures; intra-articualar fractures of the tarsals, metatarsalsm carpals and metacarpals; bunionectomies and osteotomies; arthrodeses of small joints (e.g. phalanges); fractures of the patella, ulna and radial styloid.

(6) **Technological characteristics:**

The Little Grafter™ Screw has the same technological characteristics as the predicate devices.

(7) **Performance data:**

Test results confirm that this composite screw has the requisite strength to provide both early and sustained fixation of the fracture site. Test results compare favourably with the predicate devices.

(8) **Basis for substantial equivalence:**

The Little Grafter™ Screw is equivalent in design, performance and indications to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Mr. J. Stephen Bratt
Managing Director
Biocomposites Ltd.
Etruscan Street, Etruria, Stoke-on-Trent
Staffordshire, ST1 5PQ, England

Re: K040265
Trade/Device Name: Little Grafter™ Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 6, 2004
Received: May 10, 2004

Dear Mr. Bratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040265

Device Name: Little Grafter™ Screw

Indications For Use:

The Little Grafter™ Screw is indicated for fixation of fractures of small bones and small bone arthrodeses, including, but not limited to, scaphoid fractures; intra-articular fractures of the tarsals, metatarsals, carpals and metacarpals; bunionectomies and osteotomies; arthrodeses of small joints (e.g. phalanges); fractures of the patella, ulna and radial styloid.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040265